PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

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PCT

WRITTEN OPINION
(PCT Rule 66)

Date of mailing *(day/month/year)*	20.09.2004
Applicant's or agent's file reference: P60516/001	**REPLY DUE** **within 2 month(s)** from the above date of mailing

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB 03/04086	23.09.2003	23.09.2002

International Patent Classification (IPC) or both national classification and IPC
C07C39/19

Applicant
GW PHARMA LIMITED et al.

1. This written opinion is the **second** drawn up by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

I	☒	Basis of the opinion
II	☐	Priority
III	☐	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☐	Lack of unity of invention
V	☒	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	☐	Certain documents cited
VII	☐	Certain defects in the international application
VIII	☐	Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 23.01.2005

Name and mailing address of the international preliminary examining authority:

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I. Basis of the opinion

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed")*:

Description, Pages

1-24 as originally filed

Claims, Numbers

1-24 filed with telefax on 27.08.2004

Drawings, Sheets

1/4-4/4 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   ☐ the language of publication of the international application (under Rule 48.3(b)).
   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.
   ☐ filed together with the international application in computer readable form.
   ☐ furnished subsequently to this Authority in written form.
   ☐ furnished subsequently to this Authority in computer readable form.
   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:
   ☐ the claims, Nos.:
   ☐ the drawings, sheets:

5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

6. Additional observations, if necessary:

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	Yes: 1-17; No: 18-24
Inventive step (IS)	Claims	Yes: 1-17; No: 18-24
Industrial applicability (IA)	Claims	Yes: 1-24

2. Citations and explanations

see separate sheet

1. **Re Item I** (Basis of the opinion)

1.1 Prior art

The following documents (D) are referred to in this communication; the numbering will be adhered to in the rest of the procedure:

D1: DE-A-10106024
D2: Tetrahedron Letters, Elsevier Science Publishers, Amsterdam, NI (1985), 26(8), 1083-1086
D3: WO-A-03063847
D4: GB-A-2377633
D5: WO-A-02069993
D6: WO-A-0232420
D7: WO-A-02064109

In view of their publication date, documents D3 and D4 do not contribute to prior art within the meaning of Rule 64.1(b) PCT and will not be taken into consideration.

1.2 Amendments

With Telefax dated 27.08.2004, the Applicant submitted an amended set of claims 1-24 wherein

- originally filed claims 1, 2 and 8 were combined in new claim 1
- originally filed claims 6-8 were deleted
- originally filed claim 18 has been amended according to page 5, lines 16-20 (step vii in new claim 15)
- originally filed claim 21 has been amended (new claim 18)
- originally filed claim 26 has been amended (new claim 23).

However, present claim 24 (former claim 27) refers to a 'figure 3 as shown below'. No such figure was submitted as part of the claims thereby rendering the scope of claim 24 unclear not fulfilling the requirements of Art. 19 PCT.

The requirements of art. 19 PCT are not fulfilled.

2. **Re Item V** (Reasoned statement under Rule 66.2(a)(ii) with regard to novelty,

inventive step or industrial applicability; citations and explanations supporting such statement)

2.1 Subject-matter

The present application discloses a method for obtaining cannabidiol (CBD) from plant material (independent claim 1) and a preparation of cannabidiol (independent claim 18).

2.2 Novelty

Independent claim 1 discloses a process of obtaining CBD characterized by

- obtaining a CBD-containing extract of plant material
- dissolving this extract in a solvent being a C_5-C_{12} straight chain or branched alkane or a carbonate ester of a C_1-C_1 alcohol
- removing insoluble material from this solution
- evaporating the solvent.

Claim 1 differs from
D1 in view of the solvent specified in present claim 1
D2 in view of the isolation of cannabidiol from plant material
D5 in view of the absence of a chromatographic separation used in D5
D6 in view of the absence of a high pressure column extraction used in D6
D7 in view of the isolation of CBD (see examples 17 and 18 in D7).

The subject-matter of claims 1-17 fulfills the requirements of novelty.

Independent claim 18 discloses a preparation of CBD 'prepared from plant material' characterized by a chromatographic purity of 98% or greater.

Claim 18 is to be construed as a claim to the preparation as such and does not render the claimed preparation novel merely by the fact that it is prepared from plant material.

Furthermore, a document disclosing a low molecular chemical compound and its manufacture made this compound available to the public in all grades of purity as desired by a person skilled in the art, since it is common practice for a person skilled in the art of preparative organic chemistry to further purify a compound obtained by a particular process according to the prevailing needs and requirements.

In his letter of reply dated 27.08.204, the Applicant argues that the commercially available "Sigma Standard" has a purity of 93%, indicating to a skilled man that such standard is **purified to the highest degree of purity possible**. Accordingly, the Applicant concludes that an exceptional situation exists justifying the conclusion that the high degree of purity of CBD according to claim 18 establishes novelty.

The IPEA respectfully disagrees. The circumstances for recognising such a prejudice are very strict and has normally to be demonstrated by reference to the literature of to encyclopaedias and cannot be demonstrated by a reference to a commercially available standard, which itself has to be commercially attractive.

Accordingly, the disclosures of CBD in D2 (disclosing CBD as chromatographically pure oil and as crystalline material on page 1083, 3rd paragraph), D5 (see example 1), D6 (see tables 3 and 4) and D7 (see example 18) take away the novelty of claim 18.

T***he subject-matter of claims 18-24 do not fulfill the requirements of novelty.***

2.3 Inventive step

Until claims have been received which satisfy Art. 33(2)PCT, a final decision on the inventive step of the present application cannot be taken. Accordingly, the following is provisionally pointed out:
Document D1 is at present considered as closest prior art. This document discloses in paragraphs [0008] and [0011] a process for obtaining CBD characterized by
- obtaining a CBD-containing extract of plant material
- dissolving this extract
- removing insoluble material from this solution
- evaporating the solvent.

In view of this document, the problem to be solved can be regarded as the provision of a further process for the preparation of CBD from plant material. The solution provided consists in a process according to claim 1.

The subject-matter of claim 1 is considered as involving an inventive step since none of the cited documents anticipates the use of a solvent being a C_5-C_{12} straight chain or branched alkane or a carbonate ester of a C_1-C_1 alcohol in the

work-up procedure of a cannabidiol plant extract. Furthermore, the high degree of purity obtained thereby is considered as an unexpected effect indicating an inventive step.

The requirements of Art. 33(3) PCT are fulfilled for the subject-matter of claims 1-17.

The subject-matter of claim 18 is related to a **composition**. In order to fulfill the requirements of the EPC, this composition has to be inventive *per se*.

The requirements to accord inventive step are:

1) The composition exhibits a **use** or an **effect** which is unexpected.
2) *Occasionally* when the composition has been produced by an inventive process. However, this is applicable **only** in the case where a **technical prejudice** to its production or **insurmountable difficulties** in its production were believed to exist. However, a composition is not automatically rendered inventive by an inventive process of its production.

Presently, none of the above identified criteria appear to be fulfilled.